

AD_____

AWARD NUMBER: DAMD17-00-1-0327

TITLE: Quasi-Prospective Study of Breast Cancer and Diet

PRINCIPAL INVESTIGATOR: James R. Hebert, Ph.D.
Swann A. Adams, Ph.D.

CONTRACTING ORGANIZATION: University of South Carolina
Columbia, South Carolina 29208

REPORT DATE: August 2006

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-08-2006		2. REPORT TYPE Final		3. DATES COVERED (From - To) 17 Jul 2000 – 16 Jul 2006	
4. TITLE AND SUBTITLE Quasi-Pro prospective Study of Breast Cancer and Diet				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER DAMD17-00-1-0327	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) James R. Hebert, Ph.D. and Swann A. Adams, Ph.D. E-Mail: jhebert@sc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of South Carolina Columbia, South Carolina 29208				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Conventional breast cancer (BrCA) risk factors explain 50% of variability in disease rates and change in incidence over time. The past two generations of American women have experienced major changes in physical activity, preparing and eating food, and increases in the prevalence of overweight. These factors may exert powerful influences on physiologic processes leading to cancer. This case control study aims to investigate the relationship between physical activity, diet, and adult weight history and breast cancer. Our goal is to recruit 648 incident cases of breast cancer and up to 2 controls per case from the Breast Care Centers of the Palmetto Richland and Baptist Hospitals of Palmetto Health /South Carolina Cancer Center (BCC) – services that see a total of about 35,000 mammography screenings each year and in which about 700 women are diagnosed with breast cancer. After obtaining permission from the Human Use Review Office of the USAMRAA (on 30 November 2000) to begin recruitment we finished the run-in process and began recruitment in the Palmetto Baptist Hospital BCC in spring of 2001. Recruitment at Palmetto Richland began in May 2002. As of July 31, 2005, we had recruited 1442 participants who agreed to participate of whom 742 subjects completed all study requirements.					
15. SUBJECT TERMS breast cancer, diet, physical activity, body weight, psychological factors, epidemiology, case-control study					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	17	19b. TELEPHONE NUMBER (include area code)

Army Award DAMD17-00-1-0327

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET: Final Report: Year 6 No Cost Extension

Table of Contents

Cover Page	1
SF 298	2
Table of Contents	3
Introduction	4
Specific Aims.....	4-5
Work Accomplished	5-10
Key Research Accomplishments	10
Reportable Outcomes.....	11
References	11
Appendices	12

A.1. Approved Institutional Review Board Consent Form
Data Analysis

On file:

Approved Statement of Work

Compiled Baseline Questionnaire

Compiled Coding Manual

Standard Operating Procedures

Biosketch of Project Manager

Era of Hope Poster Presentation

Revised Palmetto Women's Health Study Participant Report Summary and thank you letter

Pre-Consent Form – Teleform

Letter to Tumor Registry recruits

Phone Script for recruitment

HIPAA Waiver – Palmetto Health Alliance

Letter from South Carolina Oncologists Associates Physicians

Interim Analysis

Introduction:

It is clear from epidemiologic studies that environmental factors are largely responsible for differences in breast cancer rates across populations and changes in U.S. rates over time. Dietary factors and those related to physical activity may have powerful influences on adult weight gain and several physiologic processes that could lead to cancer. However, obtaining unbiased self-reports of these behaviors is difficult, in part because they are subject to systematic reporting errors, such as simple errors in recall and social desirability biases. This case-control study was designed to measure diet, adult weight history, and physical activity in women undergoing a diagnostic evaluation for potential breast cancer, but prior to diagnosis. The focus is on two main suspects in breast cancer: consumption of fat as a factor that could be associated with increased risk; and certain fruits, vegetables, and grains containing high concentrations of functional constituents (phytoestrogens, antioxidants, protease inhibitors, indole glucosinolates) that may be protective. High levels of adult weight gain and physical inactivity, both of which may be related to increased risk, are examined both as potential confounders to the diet exposures as well as independent predictors of breast cancer risk. The unique design of this case-control study provides a way to measure diet and other self-report measures before they can be affected by a woman's knowledge of whether or not she has breast cancer. We expect that a total of about 13,000 women will receive routine mammography for the first time in the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) over the 48-month recruitment period. Of these, about 5,400 will have confirmation by advanced diagnostic techniques, and about 20% of these will have histologically confirmed breast cancer. We projected that 60% of women coming in for advanced diagnostic techniques (N=3,240 women [20-80 yrs]), would be willing to participate, of whom one-fifth (n=648) will have been diagnosed with primary breast cancer. Age-, clinical system (i.e., Richland vs. Baptist)-, and time-matched controls will be obtained from the remaining disease-free women who visit the respective clinical sites within 3 weeks of the time that her matched case (i.e., a woman with breast cancer) enters the clinical system. Results from this investigation will add to our body of knowledge about the modifiable behaviors that are associated with incident breast cancer.

Specific Aims:

Using information from recently completed studies on sources of bias in assessment of dietary intake, this study will attempt to reconcile discrepancies between results of laboratory animal studies and cross-national comparisons strongly implicating diet as a cause of breast cancer and those from conventional epidemiologic studies that are much more equivocal on this topic. It will account for a number of covariates, especially physical activity and adult weight gain. The purpose of the proposed research is to test whether a dietary pattern associated with high-fat (generally salty or sweet) foods increases risk whereas a pattern emphasizing whole grain and vegetable intake decreases risk. This study is designed with full recognition that dietary variables are collected using assessment methods that are seen by subjects as "tests" and, therefore, are susceptible to psychological factors that are known to affect individuals in test-taking situations. Because secondary prevention will remain an important issue for the foreseeable future, it is also important that assessed populations be accessible and amenable to follow up to determine which, if any, dietary factors may be predictive of prognosis among those

diagnosed with breast cancer and to increase disease risk among those found to be free of disease at baseline. The faculty and staff of the Breast Clinic, from which all cases and the clinic-based controls will be obtained, have a keen interest in the research potential of the clinic. Given high rates and thoroughness of patient follow-up, the clinic also presents excellent opportunities to investigate the natural history of breast cancer prognoses and to follow up breast cancer patients.

The primary goal of the proposed research is to investigate the role of diet and adult weight gain, with historical levels of activity being obtained to “characterize prior activity” to use as an adjustment for confounding in the etiology of breast cancer. The secondary goal of the research will be to assemble cohorts of disease-free, high-risk women and breast cancer patients to: 1. establish breast cancer risk factors in women at high risk because of either a family history of the disease or presence of a precancerous lesion (i.e., women determined not to have breast cancer at the time of enrollment); and 2. delineate lifestyle, psychosocial and/or treatment factors that might affect prognosis in women with a histologically confirmed cancer of the breast, as we have done previously ^{1, 2}.

Work Accomplished:

The approved Statement of Work (see Appendix 1) categorized the work objectives for the project into four discrete tasks, each with indications for the months from the study timeline in which these tasks will be accomplished. Due to unforeseen delays in getting Human Subjects approval from the Institutional Review Boards of the three bodies governing this research [(i.e., U.S. Army, University of South Carolina, and the Palmetto Health Alliance (now Palmetto Health)], the original study timeline was revised. The original timeline started in July 2000 (month 1) and participant recruitment was scheduled to begin in January 2001 (month 7). Final approval from all three institutions was not obtained until late February 2001, with recruitment beginning at Palmetto Baptist in the spring of 2001 and at the Richland Hospital campus of Palmetto Health in the spring of 2002. Full-scale recruitment at Richland began with the post-vacation flow of work in September 2002.

With improvements in diagnostic procedures and concomitant reductions in the interval between first contact with the clinical system and diagnosis, we had to modify our study design as described below. The recruitment continues to proceed well. Though not at the pace originally envisaged, it has improved considerably and we intend to continue to recruit subjects, at our own expense, until December 2006. As a consequence of the design change, we have taken the opportunity to begin looking at the existence of bias in reporting health-related behaviors and will use these data in formal testing of study hypotheses, as we have done in previous work in BrCA studies. Differences in BMI (kg/m^2) of enrollees vs. screenees (but not cases vs. controls) indicate selection bias in overall enrollment into the study. Although we will not complete final data analyses until 2007, we have observed results confirmatory of other studies (i.e., higher breast cancer rates in the more educated and in Whites). Higher likelihood of BrCA in widowed women and lower likelihood in divorced and separated women are intriguing. Results indicating protection with more vigorous physical activity outside of the home and with more household activity are also consistent with those observed in other studies. There appear to be some differences emerging in terms of intakes of specific food groups, which will need to be monitored when we analyze the final data early in 2007. Initial results on the DNA from buccal

cells indicates sample adequacy from those specimens that were collected. A major tissue banking effort began in 2004 and we now are able to link to those data in order to conduct studies beyond the scope of what we originally intended and proposed.

In the following sections, each individual sub-task outlined in the Statement of Work (Appendix 1) is indicated in bold text and by a an alphabetic indicator (e.g., a, b, c,...). Our work to accomplish these sub-tasks follows in bulleted form. Where applicable, problems encountered in completing tasks are described and our plans for overcoming these barriers are outlined. Most of these remain unchanged from last (2005) annual report.

Task 1: Run-in Phase, Months 1-6 (July-December 2000):

a) Review baseline lifestyle and demographic questionnaire for completeness and for content validity.

- An initial Baseline questionnaire was complied (Appendix 2) and included the following sections
 - Demographics
 - Food Frequency Questionnaire
 - Physical Activity Assessment (Lifetime, Past-Year)
 - Medical/Family History
 - Personal Reaction Inventory (also known as the Marlowe Crowne Social Desirability Scale)
 - Martin-Larsen Approval Motivation scale (to measure social approval)
 - SF-36 Quality of Life

b) Revise baseline questionnaire as necessary.

- During questionnaire development phase, considerable refinement was made to several aspects of the baseline questionnaire in order to meet the objectives of this investigation and provide additional information about modifiable risk factors for breast cancer not specifically outlined in the original application (as secondary analyses)
 - The scope of the original FFQ was expanded to measure more effectively vegetable and fruit consumption in enough detail to evaluate specific dietary hypotheses
 - Two Physical Activity Assessments were adapted for self-administration
 - Sections on medical and family history were lengthened to support further research into the impact of sleep patterns, non-steroidal anti-inflammatory drugs, and various lifestyle factors on breast cancer development
- Ten clinic nurses pilot tested the baseline questionnaire in order to check for readability and relevance, as well as to assess the feasibility of administering a lengthy instrument to study participants.
- Pilot questionnaire data were also used to test questionnaire scanning software and SAS programming files. Data quality also was assessed from these pilot data.

c) Hire and train the Research Assistant.

- We currently employ two part time graduate assistants (1 PhD and 1 Masters candidates) and 2 assistants to recruit (Public Health Students from Benedict College, a HBCU) and collect data in the field and for data management tasks.
- A Data Manager is currently overseeing all aspects of data processing.

d) Develop a Manual of Operations (MOP), a detailed document describing data management systems.

- The MOP has been completed: and revisions were made as needed. (None required during this reporting period)
- The MOP's content is based on our successful experience with other large-scale epidemiologic studies, and describes how SAS, Teleform (optical scanning software), Excel, EpiInfo and other data management/tracking software are effectively integrated to manage and analyze the data.
- A Coding Manual was compiled and checked for accuracy.
- Standard Operating Procedures were developed to ensure that; participants are effectively and ethically recruited; high quality data are collected during the patient visits, and that data are efficiently and accurately entered for analysis.
- Security measures have been implemented to protect all participant information.

e) Develop and pilot test the participant tracking database, as well as all measurements and documenting procedures.

- A participant-tracking database has been constructed and is functioning in support of our recruitment and monitoring efforts.

f) Train staff in all data-related and clinic-based procedures.

- Staff is retrained on a regular basis to ensure quality data management and optimal procedures for participant recruitment, clinical measurements, and security.

Task 2: Recruitment, Months 7-48:

a) Of the 5,400 women visiting the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) for an advanced diagnostic work-up to rule in or rule out breast cancer, enroll 60% (3,240 women) as participants for the study.

As noted in the introduction, due to changes in regulations and the clinical system, it has been necessary to modify the recruitment strategy over time. We currently have settled on Strategy #3 as the final one that will be used for the duration of the study. We provide the three options considered as a permanent note for the record.

Strategy #1

Patients entering the clinical system for a screening mammogram were asked to complete a consent for telephone contact. Approximately 20% of the women were asked to return to the clinic for a diagnostic work-up for positive radiographical findings. Those patients who had agreed to contact upon screening were contacted and asked to participate.

Problems: Only 1/3 of patients who were scheduled for diagnostic work-up were referred from screening. The other 2/3 were patients referred by family physicians or Ob/Gyn physicians for suspicious symptoms (i.e. palpable mass). These patients did not have the opportunity to sign the consent for contact.

Strategy #2

Instead of telephone contact, we recruited participants as they waited for their diagnostic appointment in the clinic. No consent would be needed to talk with patients about their participation.

Problems: Although the response was positive, we were dependent upon the waiting time at the clinic. For instance, if the schedule was heavily booked, wait times were increased and participation increased. With less waiting time, patients were less inclined to participate. Other patients indicated that they would like to participate, but could not make a decision at that time because of anxiety associated with a diagnostic work-up. We also discovered that case recruitment did not meet expectations based upon clinic statistics. Thus providing further evidence that the anxiety associated with the appointment was preventing study participation.

Strategy #3

With improvements in diagnostic procedures and concomitant decreases in waiting time, most patients were completing the survey aware of their breast cancer status. Thus, the recall bias that we had hoped to avoid with the original study design was not possible. This necessitated the latest change in which cases and controls would be recruited via different clinical routes. Because of these changes in practice patterns, it was determined that we could go somewhat farther “downstream” to the oncology practice. Virtually all oncologists in the Midlands (the catchment area for the three tertiary care facilities serving the central portion of the state) practice out of South Carolina Oncology Associates (SCOA). Currently, SCOA has offices in each of the hospitals. At the end of 2003, they moved to a single practice site, which is centrally located in relation to the hospitals. Patients receive all outpatient treatment at this site. In the past year SCOA, has combined their three offices and formed one central office. We still continue to be able to recruit from their patient pool and also to conduct clinical appointments which makes it easier for the patients to keep their appointments since the appointments are scheduled around their doctor’s appointments and treatment.

In order to increase the accuracy of data collected, 2/3 of the questionnaires are administered by study personnel. This has assisted with retention of study participants by lessening the amount of time the participants had to spend completing the questionnaire at home. By using this method, more participants on average are completing the study and the participants are completing in a timely manner. Participants are mailed the demographics portion of the

questionnaire and complete it at home. When they come in for their clinic appointment to have their measurements taken, study personnel administer the food frequency portion. The study personnel then call the participants and administer the physical activity portion over the phone during a scheduled call.

Cases: are now recruited within 6 months of diagnosis. Places of contact for recruitment of breast cancer cases are the hospital tumor registry, oncologist office, breast health nurse, surgical service, and radiation oncology. We receive monthly downloads from the largest patient pool, the Cancer Data Management Department (Tumor Registry), which accounts for approximately 80% of breast cancer diagnosis in the metropolitan Columbia area.

Controls: Because recruitment at the diagnostic appointment was not proving to be the optimal time to approach patients for participation, we will recruit controls via telephone recruitment after a screening or diagnostic appointment. Both mammography clinics will obtain consent for contact from all patients coming to the clinic for either a screening mammogram or diagnostic work-up. Those consenting to contact are placed in a database for telephone contact. Controls will be matched to cases on the hospital/clinic at which they were originally seen.

b) Using instruments described in section 4.2., collect data on: diet, physical activity, and other aspects of lifestyle; demographic variables; family and personal health-related history; and social desirability and social approval.

- Of the **xxxx** participants agreeing to participate and to whom questionnaires were provided, **xxxx** participants have completed the study. A protocol is in place to follow up with participants who have not completed the study.

c) Collect and bank pre-diagnostic blood, urine, and buccal and breast tissue samples among a subset for future molecular epidemiologic analyses and biochemical validation of dietary assessment procedures, to be funded by future ancillary projects.

- Isolation and purification of genomic DNA from buccal cells was carried out on samples of seven patients, which were randomly chosen.
- The technique used was the phenol-chloroform extraction method for purification of DNA. Polymerase chain reaction (PCR) was used to amplify genomic DNA and agarose gel electrophoresis performed. The gel showed the presence of DNA, but since we were not specifically looking for any nucleic acid sequences the PCR technique was used just to confirm the presence of DNA in the samples.
- The collection method of DNA was found to be effective in getting substantial amount of DNA after PCR. The samples were stored in 70% ethanol. Changes in storage procedures like change in storage vials, processing with EDTA and then storing for future use in 70% ethanol is recommended, for efficient processing and isolation of DNA.
- There is currently no protocol in place to continue biological samples.

d) Take anthropometric measurements, as described in section 4.3.

- ***Rx-update***% of participants recruited have had anthropometric measurements taken.

e) Abstract medical records for relevant health history and pathology data.

- As part of the new recruitment procedures, we obtain monthly downloads from the Cancer Data Management department (Tumor Registry) that includes the pathology section of the medical record, patient identifiers (for linkage), and other relevant data.

Task 3: Data Entry, Verification, and Interim Analyses, Months 7-48:

a) Flag all outlier and illogical responses.

- Most of the questions in the PWHs questionnaire require that the study participant fill in the bubbles with pencil. There are a few questions that require them to write numbers (for recalled previous weight, height, etc). Once the questionnaires are received from the study participants the study staff look for any stray pencil marks that may cause incorrect values to be output when they are scanned. After this check and making corrections if any, the questionnaires are scanned using the Teleform software. A verification process is built into the software that allows the study staff to verify the scanned data with the actual questionnaire. After the verification process is completed the software outputs the data into a 'Comma Separated Value' (CSV) file.
- Towards the process of creating an analytic dataset SAS programs have been written to read these CSV files and to look for errors in the data. Multiple programs have been written to check individual sections of the questionnaire. The program written to read in the measurements collected in the clinic checks for extreme values of height, weights, and other body measurements. If any extreme values are detected the study staff check the actual clinic form to verify and correct the information if there is an error. Once the clinic data has been checked and any errors corrected the data is output into an analytic dataset. As participants are enrolled into the study the same process is followed and the data is appended to the original dataset.
- SAS programs have also been written to check for consistency of the physical activity data collected in the questionnaires. These programs calculate the number of hours a participant has spent in a certain category of activity per day. Similarly programs have been written to identify outliers in the Food Frequency Questionnaire (FFQ). The program calculates the number of servings of the different food groups (based on USDA recommendations) and looks for outliers in these data.
- We send the participants a report with results based on their clinic measurements and on the physical activity data.

b) Verify all outlier and illogical responses, re-contacting participants, if necessary.

- Up until this point we have not encountered any critical errors that have required us to re-contact the participants.

c) Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

- An interim analysis has been completed as of 15 August 2006. See tables in attached appendix.

d) At months 13, 25, and 37 conduct multivariable analyses, as described in section 4.8. of the proposal.

- All previous sections (a, b, c) have been implemented in order to prepare for this task.
- As noted above, final recruitment will not be complete until December 2006. We will conduct hypothesis testing and ad hoc analyses of other data early in 2007. However, as noted we have conducted descriptive interim analyses as of 15 August 2006.

Key Research Accomplishments:

Currently, we have been collaborating with Palmetto Health on the design and implementation of a research database and utilizing their cancer data management system to its fullest potential. As the result of recent HIPAA guidelines, we have developed and implemented a research database that will greatly benefit this study as well as future studies. In this process, we have developed an optically scannable pre consent form, which greatly decreases staff effort on data entry and increase data accuracy. We are currently working towards the South Carolina Cancer Center, collaboration between Palmetto Health Alliance and the University of South Carolina, maintaining this research database so that it can be used for future studies. Other studies have already been able to utilize this resource.

Reportable Outcomes:

Study products: There have been a considerable number of data collection instruments and recruitment and informational materials that have been produced in the first year of the study (see appendices). As no such study has been attempted in South Carolina previously, the existence of these instruments and materials has far-reaching implications. We currently have approximately 10 research studies that have or will utilize the survey instruments developed through this award. Additionally, each patient is given a report of her anthropometric, physical activity, and dietary data along with an explanation of what these values mean. We also are planning to write a paper with the Cancer Data Management department team on recruitment of cases through their rapid ascertainment system.

Funding applied for and received based on this award:

Our Co-Principal Investigator, Dr. Swann Adams, was funded for her grant entitled “Physical Activity and Hormone Receptor-Defined Breast Cancer” by the American Colleges Sports Medicine Paffenbarger Grant. Still other grants that Dr. Adams has received based upon work accomplished with this grant were “Ethnicity, Follow-up, and Breast Cancer Outcomes Among

Economically Disadvantaged Women” from the University of South Carolina and “A Pilot And Feasibility Study Of Ethnic Differences In Interval Diagnosed Breast Cancers In South Carolina” funded by the South Carolina Cancer Center. She has currently has 2 other grants pending which build upon the work accomplished with the award.

A Co-Principal Investigator, Dr. Joan Cunningham, was awarded a grant by the South Carolina Research Initiative entitled "Cancer Prevention Drug Discovery for Breast and Colon Cancer".

Training opportunities: there currently are three graduate assistants (1 doctoral student from the College of Nursing and 2 masters' student in the Department of Epidemiology and Biostatistics at the Arnold School of Public Health) who are working on various aspects of this study. We also employ two students from Benedict College, a minority college in the area.

Planned applications?

- 1) Follow-up QOL and body composition outcomes at 12- and 24-months, post-diagnosis
- 2) Follow-up recurrence?
- 3) Physical Activity and Hormone Receptor-Defined Breast Cancer

References:

1. Hebert JR, Hurley TG, Ma Y. The effect of dietary exposures on recurrence and mortality in early stage breast cancer. *Breast Cancer Res Treat* 1998;51:17-28.
2. Hebert JR, Augustine A, Barone J, Kabat GC, Kinne DW, Wynder EL. Weight, height and body mass index in the prognosis of breast cancer: early results of a prospective study. *Int J Cancer* 1988;42:315-318.

Appendices:

- Descriptive Analyses

On file:

- Approved Statement of Work
- Compiled Baseline Questionnaire
- Compiled Coding Manual
- Standard Operating Procedures
- Biosketch of Project Manager
- Era of Hope Poster Presentation
- Revised Palmetto Women's Health Study Participant Report Summary and thank you letter
- Pre-Consent Form – Teleform
- Letter to Tumor Registry recruits
- Phone Script for recruitment
- HIPAA Waiver – Palmetto Health Alliance
- Letter from South Carolina Oncologists Associates Physicians
- Interim Analysis

Appendix 1 – Descriptive Analyses

Table 1. Participant demographic characteristics of the Palmetto Women's Health Study

Variable	Case % (n=208)	Control % (n=447)	p-value
Education			
≤ Highschool	22.3	17.0	0.04
Some college	35.4	32.0	
College Completed	16.5	26.3	
More than College	25.7	24.7	
Employment Status			
Full-time	45.9	57.5	0.02
Part-time	14.5	12.7	
Unemployed	39.6	29.9	
Paternal Race			
White	75.5	21.4	0.24
African American	20.6	16.7	
Hispanic	.5	0.5	
Native American	2.0	0.5	
Other	1.5	0.9	
Maternal Race			
White	76.0	80.7	0.37
African American	22.1	16.6	
Hispanic	1.0	1.1	
Native American	0	0.7	
Other	1.0	0.9	
Menopausal Status			
Pre Menopausal	30.5	42.6	0.004
Post Menopausal	69.5	57.	
1st Degree Relative with Breast Cancer			
Yes	12.0	12.2	0.95
No	88.0	87.8	
Ever Pregnant			
Yes	88.2	82.9	0.08
No	11.8	17.1	

Table 2. Participant reproductive and anthropometric characteristics of the Palmetto Women's Health Study

Variable	Case Mean (SD) n=208	Control Mean (SD) n=447	p-value
Age	55.9 (11.0)	51.1 (11.9)	<0.0001
Age at 1st Menses	12.4 (1.7)	12.4 (1.9)	0.77
Age at 1st Pregnancy	22.9 (5.5)	23.5 (5.7)	0.26
Height (cm)	162.7 (6.8)	162.6 (6.1)	0.91
Weight (kg)	73.6 (17.8)	72.4 (17.2)	0.41
Body Mass Index	27.8 (6.6)	27.4 (6.4)	0.51
Waist to Hip Ratio	0.81 (0.08)	0.78 (0.09)	0.0002
Percent Body Fat	37.5 (7.4)	36.4 (7.4)	0.10

Table 3. Diet and physical activity characteristics of participants in the Palmetto Women's Health Study.

Variable	Case Mean (SD) n=208	Control Mean (SD) n=447	p-value
Food Group (servings/day)			
Alcohol	0.1 (0.3)	0.2 (0.4)	0.31
Fruit	2.2 (1.8)	2.0 (1.7)	0.25
Vegetable	2.9 (1.7)	3.1 (2.2)	0.15
Bread, Cereals, Pasta	2.4 (1.4)	2.6 (1.6)	0.11
Beans	0.2 (0.3)	0.3 (0.5)	0.17
Fish	0.3 (0.3)	0.3 (0.6)	0.19
Meat, Poultry, Egg	1.6 (1.1)	1.6 (1.2)	0.99
Milk, Yogurt, & Cheese	1.3 (1.1)	1.5 (1.3)	0.11
Type of Physical Activity (hours/week)			
Recreational	2.3 (3.7)	2.4 (3.2)	0.67
Occupational/Volunteer	8.6 (11.4)	8.2 (10.1)	0.62
Household	9.8 (7.5)	9.4 (7.8)	0.49
Lawn & Garden	1.2 (2.5)	1.3 (3.0)	0.63

Table 4. Multivariate Modeling of Breast Cancer Risk- Palmetto Women's Health Study

Variable*	Odds Ratio	Confidence Interval
Alcohol Consumption	1.25	0.74 - 2.12
Bean Consumption	1.35	0.87 - 2.10
Bread, Cereal, & Pasta Consumption	1.09	0.97 - 1.23
Fish Consumption	1.31	0.76 - 2.25
Fruit Consumption	0.96	0.88 - 1.06
Meat Consumption	0.99	0.86 - 1.15
Milk, Cheese, & Yogurt Consumption	1.13	0.96 - 1.32
Vegetable Consumption	1.08	0.99 - 1.18
Household Activity	0.99	0.97 - 1.02
Lawn & Garden Activity	1.02	0.96 - 1.08
Recreational Activity	1.01	0.96 - 1.06
Occupational/Volunteer Activity	1.00	0.98 - 1.02
Body Mass Index	0.99	0.97 - 1.02
Percent Body Fat	0.98	0.96 - 1.01

All models were adjusted for menopausal status and 1st degree relative with breast cancer